

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A method for determining a chemotherapeutic regimen for an individual having a primary and metastatic tumor, comprising
 - a) obtaining a ~~mRNA sample from the individual's~~ primary tumor specimen;
 - b) determining expression levels of a tumor gene determinant comprising
 - 1) determining mRNA levels of the tumor gene determinant in the primary tumor sample
 - 2) comparing the amount of tumor gene determinant mRNA levels in the primary tumor sample from step 1) to an amount of mRNA of an internal control gene; and
 - c) determining a chemotherapeutic regimen for the individual based on the amount of tumor gene determinant mRNA in the primary tumor sample and a predetermined threshold level for the tumor gene determinant.
 - ~~b) determining a gene expression level for a tumor gene determinant in the primary tumor specimen;~~
 - ~~c) comparing the gene expression level for the tumor gene determinant with a predetermined threshold value for that tumor gene; and~~
 - ~~d) providing a chemotherapeutic regimen comprising a chemotherapeutic agent appropriate for the tumor gene determinant to treat the individual having a tumor metastases.~~
2. (Original) The method of claim 1 wherein the tumor gene determinant is EGFR.
3. (Cancel)
4. (Cancel)
5. (Original) The method of claim 1 wherein determining ~~gene~~ gene expression levels of a tumor gene determinant comprises a fluorescence based real-time detection method.

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6. (Original) The method of claim 5 wherein the tumor gene determinant is EGFR.
7. (Cancel)
8. (Cancel)
9. (Cancel)
10. (Cancel)
11. (Cancel)
12. (Cancel)
13. (Cancel)
14. (Cancel)
15. (Cancel)
16. (Cancel)
17. (New) A method for determining a chemotherapeutic regimen for an individual having a primary and metastatic tumor, comprising
 - a) obtaining a primary tumor specimen and fixing the specimen to obtain a fixed tumor specimen;
 - b) determining a gene expression level for a tumor gene determinant in the fixed primary tumor specimen, comprising
 - 1) isolating mRNA for a tumor gene determinant from the fixed tumor specimen, wherein the fixed tumor sample is heated in the presence of an effective amount of a chaotrophic agent and wherein the heating occurs at a temperature from about 50°C to about 100°C;

- 2) subjecting the mRNA to amplification using a pair of oligonucleotide primers capable of amplifying a region of the tumor gene determinant to obtain an amplified sample;
 - 3) determining the amount of tumor gene determinant mRNA in the amplified sample;
 - c) comparing the amount of tumor gene determinant mRNA from step 3) to an amount of mRNA of an internal control gene; and
 - d) determining a chemotherapeutic regimen for the individual based on the amount of tumor gene determinant mRNA in the primary tumor sample and a predetermined threshold level for the tumor gene determinant.
18. (New) The method of claim 17 wherein the tumor gene determinant is EGFR.
19. (New) The method of claim 18 wherein the pair of oligonucleotide primers consist of the SEQ ID NO:1 or an oligonucleotide primer at least about 80% identical thereto and SEQ ID NO:2 or an oligonucleotide primer at least about 80% identical thereto.
20. (New) The method of claim 19 wherein determining expression levels of a tumor gene determinant comprises a fluorescence based real-time detection method.
21. (New) A method for treating a metastatic tumor with a chemotherapeutic regimen in an individual having a having a primary and metastatic tumor, comprising
- a) obtaining a primary tumor specimen and fixing the specimen to obtain a fixed tumor specimen;
 - b) determining a gene expression level for a tumor gene determinant in the fixed primary tumor specimen, comprising
 - 1) isolating mRNA for a tumor gene determinant from the fixed tumor sample, wherein the fixed tumor sample is heated in the presence of an effective amount of a chaotrophic agent and wherein the heating occurs at a temperature from about 50°C to about 100°C;
 - 2) subjecting the mRNA to amplification using a pair of oligonucleotide primers capable of amplifying a region of the tumor gene determinant to

- obtain an amplified sample;
 - 3) determining the amount of amplified tumor gene determinant mRNA in the amplified sample;
 - c) comparing the amount of tumor gene determinant RNA from step 3) to an amount of mRNA of an internal control gene; and
 - d) determining a chemotherapeutic regimen for the individual based on the amount of tumor gene determinant mRNA in the amplified sample and a predetermined threshold level for the tumor gene determinant,
 - e) providing a chemotherapeutic regimen appropriate for the gene expression levels of the tumor gene determinant in the amplified sample of the primary tumor specimen.
22. (New) The method of claim 21 wherein the tumor gene determinant is EGFR.
23. (New) The method of claim 22 wherein the pair of oligonucleotide primers consist of the SEQ ID NO:1 or an oligonucleotide primer at least about 80% identical thereto and SEQ ID NO:2 or an oligonucleotide primer at least about 80% identical thereto.
24. (New) A method for determining a chemotherapeutic regimen for an individual having a primary and metastatic tumor, comprising
- a) obtaining a primary tumor specimen;
 - b) fixing and paraffin embedding (FPE) the primary tumor specimen;
 - c) deparaffinizing the tumor specimen to obtain a deparaffinized sample;
 - d) determining gene expression levels for a tumor gene determinant in the deparaffinized sample of the primary tumor specimen, comprising
 - 1) isolating tumor gene determinant mRNA from the deparaffinized sample, wherein said sample is heated to a temperature in the range of about 50°C to about 100°C; and
 - 2) determining the amount of tumor gene determinant mRNA by amplifying the mRNA using a pair of oligonucleotide primers capable of amplifying a region of the tumor gene determinant to obtain an amplified sample
 - e) comparing the amount of tumor gene determinant mRNA from step d) to an amount

- of mRNA of an internal control gene; and
 - f) determining a chemotherapeutic regimen for the individual based on the amount of tumor gene determinant mRNA in the amplified sample and a predetermined threshold level for the tumor gene determinant.
25. (New) A method for determining a chemotherapeutic regimen for an individual having a primary and metastatic tumor, comprising
- a) obtaining a primary tumor specimen;
 - b) fixing and paraffin embedding (FPE) the primary tumor specimen;
 - c) deparaffinizing the tumor specimen to obtain a deparaffinized sample;
 - d) determining gene expression levels for EGFR in the primary tumor specimen, comprising
 - 1) isolating mRNA from the deparaffinized sample, wherein said sample is heated to a temperature in the range of about 50°C to about 100°C; and
 - 2) determining the amount of EGFR mRNA by amplifying the mRNA using an oligonucleotide primer SEQ ID: 1, or an oligonucleotide primer at least 80% identical therewith and hybridizes to a complement of SEQ ID NO: 1 under stringent conditions; wherein said isolated and purified oligonucleotide is capable of amplifying a portion of the 5' untranslated region and Exon 1 of EGFR mRNA isolated from fixed and paraffin embedded (FPE) tissue when used with SEQ ID NO: 2, and;
SEQ ID: 2 or an oligonucleotide primer at least 80% identical therewith and hybridizes to a complement of SEQ ID NO: 2 under stringent conditions; wherein said isolated and purified oligonucleotide is capable of amplifying a portion of the 5' untranslated region and Exon 1 of EFGR mRNA isolated from fixed and paraffin embedded (FPE) tissue when used with SEQ ID NO: 1, and
 - e) comparing the amount of EGFR mRNA from step d) to an amount of mRNA of an internal control gene; and
 - f) determining a chemotherapeutic regimen for the individual based on the amount of EGFR mRNA in the amplified sample and a predetermined threshold level for the EGFR.

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26. (New) The method of claims 20 or 25, wherein the mRNA is isolated in the presence of an effective amount of chaotropic agent.
27. (New) The method of claim 20, 23, 24, or 25 wherein the heating occurs at a temperature from about 75°C to about 100°C for a period of about 5 to about 120 minutes.